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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/627,029  | 07/24/2003  | Niclas Hogberg       | B0051-US02          | 3700             |
| 24994   | 7590        | 12/07/2005           | EXAMINER            |                  |
| GAMBRO, INC<br>PATENT DEPARTMENT<br>10810 W COLLINS AVE<br>LAKEWOOD, CO 80215 |             |                      | KIM, SUN U          |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1723                |                  |

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/627,029 | <b>Applicant(s)</b><br>HOGBERG ET AL. |  |
|                              | <b>Examiner</b><br>John Kim          | <b>Art Unit</b><br>1723               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-26 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-23, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 10/000,185.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/24/03, 1/16/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "METHOD FOR PROCESSING A BLOOD PRODUCT WITH A BAG SET HAVING A MULTI-WAY CONNECTOR".

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3. The disclosure is objected to because of the following informalities:

On page 1, as the first sentence after the title, “This application claims the benefit U.S. Patent Application Serial Number 10/000,185, filed November 30, 2001, which claimed the benefit of International PCT Application No. PCT/SE00/01076 filed 26 May 2000,” should be changed to “This application is **a Division** of U.S. Patent Application Serial Number 10/000,185, filed November 30, 2001, **now U.S. Patent No. 6,656,105**, which is **a Continuation** of International PCT Application No. PCT/SE00/01076 filed 26 May 2000”.

Appropriate correction is required.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 7 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by McMannis et al (U.S. Patent No. 5,368,542). McMannis et al teach a bag set comprising a ring-shaped processing bag (136) interconnected to multiple containers via a tubing harness (172) with valves (312) on multiple connecting tubes i.e. a multi-way connector wherein the connecting tubes to a tubing harness (172) include a solution tube (174) from an adapter (170) connected to a gradient solution and a connecting tube (174) from a bag (296) having the source of cell medium product be processed and a connecting tube (174) connected to the ring-shaped bag (136) via axial entry port (164) which function as claimed ring inlet tube as well as ring outlet tube to provide flow of processed product to a processed component bag (300, 304, 308) (see figures 3, 6; col. 9, lines 44-55; col. 10, line 9 – col. 11, line 51; col. 13, lines 12-38). Recitations of “adapted to” phrases

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in claim 7 are of no patentable consequence because it has been held that the recitation that an element is “adapted” to perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 7-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-12 of U.S. Patent No. 6,740,239. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1 and 7-12 of U.S. Patent No. 6,740,239 fully suggest the claims 7-13 of the instant application.

8. Claims 14-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-11 of U.S. Patent No. 6,740,239 in view of U.S. Pat. No. 5,723,050 (Unger et al.) Claims 14-23 essentially differ from the method of U.S. Patent No. 6,740,239 in reciting various steps of flowing blood product from the ring bag to the processed component bag including above step while the step of processing continues, sensing a blood product during the processing of blood including centrifugation, clamping, sealing or cutting a connecting tube between the ring bag and the component bag. Unger et al teach the centrifugal blood separation method comprising the steps of flowing processed blood components from a ring bag (1) in a ring chamber (32) into two bags (2) via a connecting tube (3) with a branched conduits having clamp valves (38, 39) controlled by photocells which detect displacement of the boundary surface of the phase in the connection tube (3) during on-going centrifugation (see figures 1, 7-8; col. 5, lines 23-27; col. 6, line 62 – col. 8, line 65). Sealing or cutting a connecting tube are well-known steps in the art of blood processing to remove processed blood components from a bag set. It would have been obvious to a person of ordinary skill in the art to

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incorporate well-known claimed steps in the blood processing method as disclosed in Unger et al in the method of U.S. Patent No. 6,740,239 to effectively separate processed blood components from the blood.

9. Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

J. Kim  
December 2, 2005